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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,725	08/06/2003	Stuart Neil Prince	1324030A	8868

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EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/635,725	Applicant(s) PRINCE ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to for the following informalities: page 5, paragraph 22, "f*or" should be changed to "for". Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-16 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "at least a portion". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "at least a portion" cannot be ascertained. Clarification as to the meaning of this term is required.

It should be noted that *Bacillus larvae* is now known as *Paenibacillus larvae* as evidenced by Heyndrickx et al (*Int J Syst Bacteriol*, October 1996, 45(4):988-1003).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 7-16 are rejected under 35 U.S.C. 102(b) as anticipated by Oldroyd et al (*Aust J Agric Res*, 1989, 40(3), p. 691-698).

Claims 1 and 7-16 are drawn to a composition for the treatment or prophylaxis of bee disease, the composition comprising an inoculum and an apicultural delivery vehicle.

Oldroyd et al teach that honeybee colonies were treated with various oxytetracycline hydrochloride (OTC) preparations at the same time of inoculation with *Bacillus larvae* spores. Oldroyd et al teach that colonies were inoculated with a comb (apicultural delivery vehicle) containing larvae sprayed with 20 ml of *Bacillus larvae* (page 692). Claim limitations such as "the composition of claim 1, wherein the inoculum comprises one or more microorganisms that produce one or more antibiotics active against one or more bee pathogens", "the composition of claim 7, wherein the antibiotics are active against at least one of *Melissococcus pluton* and *Paenibacillus larvae subsp. larvae*", "the composition of claim 7, wherein the antibiotics) are bacteriolytic" and the composition of claim 7, wherein the antibiotics are the anti-*Melissococcus pluton* and/or the anti-*Paenibacillus larvae subsp. larvae* antibiotics found in *Paenibacillus larvae subsp. pulvaciens* would be inherent in the teachings of the prior art. The composition of Oldroyd et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the

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same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

4. Claims 1 and 7-16 are rejected under 35 U.S.C. 102(b) as anticipated by Hansen et al (*Tidsskrift for Planteavl*, 1988, Vol. 92, No. 1, p. 11-15).

Claims 1 and 7-16 are drawn to a composition for the treatment or prophylaxis of bee disease, the composition comprising an inoculum and an apicultural delivery vehicle.

Hansen et al teach that honeybee colonies were inoculated with *Bacillus larvae* spores by eating honey (apicultural delivery vehicle) infected with the *B. larvae* spores (page 11). Hansen et al teach that some colonies that received the *Bacillus larvae* did not show clinical symptoms of *B. larvae* infection (page 11). Claim limitations such as “the composition of claim 1, wherein the inoculum comprises one or more microorganisms that produce one or more antibiotics active against one or more bee pathogens”, “the composition of claim 7, wherein the antibiotics are active against at least one of *Melissococcus pluton* and *Paenibacillus larvae subsp. larvae*”, “the composition of claim 7, wherein the antibiotics are bacteriolytic” and the composition of claim 7, wherein the antibiotics are the anti-*Melissococcus pluton* and/or the anti-*Paenibacillus larvae subsp. larvae* antibiotics found in *Paenibacillus larvae subsp. pulvificiens* would be inherent in the teachings of the prior art. The composition of Hansen et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

5. Claims 1 and 7-16 are rejected under 35 U.S.C. 102(b) as anticipated by Wilson et al (*Can J. Microbiol.*, June 1970, 16(6) 521-526).

Claims 1 and 7-16 are drawn to a composition for the treatment or prophylaxis of bee disease, the composition comprising an inoculum and an apicultural delivery vehicle.

Wilson et al teach that honeybee colonies were inoculated with *Bacillus larvae* spores (page 522). Wilson et al teach that colonies were inoculated by eating *B. larvae* infected glandular food (apicultural delivery vehicle) containing *B. larvae* (page 522). Claim limitations such as "the composition of claim 1, wherein the inoculum comprises one or more microorganisms that produce one or more antibiotics active against one or more bee pathogens", "the composition of claim 7, wherein the antibiotics are active against at least one of *Melissococcus pluton* and *Paenibacillus larvae subsp. larvae*", "the composition of claim 7, wherein the antibiotics) are bacteriolytic" and the composition of claim 7, wherein the antibiotics are the anti-*Melissococcus pluton* and/or

the anti-*Paenibacillus larvae subsp. larvae* antibiotics found in *Paenibacillus larvae subsp. pulvificiens* would be inherent in the teachings of the prior art. The composition of Wilson et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejection - 35 USC §102/ 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 1-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as anticipated by Hooperingarnar et al (*American Bee Journal*, 1988, Vol. 128, No. 2, p. 120-121).

Claims 1-16 are drawn to a composition for the treatment or prophylaxis of bee disease, the composition comprising an inoculum and an apicultural delivery.

Hooperingarnar et al teach that bee colonies were sprayed with syrup containing *Bacillus larvae* spores (page 120). Hooperingarnar et al teach that the colonies were treated with Terramycin (oxytetracycline hydrochloride) mixed in syrup, sprays, extender patties or sugar dust (page 120).

Hooperingarnar et al do not specifically disclose a composition comprising a *Bacillus larvae* inoculum and an apicultural delivery vehicle that is a patty or a dusting or a paste or a spray. However, Hooperingarnar et al disclose that compositions for the treatment of American foulbrood can be delivered using apicultural delivery vehicles such as a patty, a dusting, a spray or a paste.

It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use a suitable apicultural delivery vehicle to deliver the composition comprising *Bacillus larvae* for the treatment or prophylaxis of a bee disease because Hooperingarnar et al have demonstrated that compositions for the treatment of American foulbrood can be delivered using apicultural delivery vehicles such as a patty, a dusting, a spray or a paste.

Pertinent Prior Art

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure (*Hansen et al, Apidologie, Nov-Dec 1998, Vol. 29, No. 6, pp., 569-578*).

Status of Claims

8. No claims are allowed.

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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April 12, 2005



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